

**STATE OF MICHIGAN**  
**DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS**  
**OFFICE OF FINANCIAL AND INSURANCE REGULATION**  
**Before the Commissioner of Financial and Insurance Regulation**

**In the matter of**

**XXXXXX**

**Petitioner**

**v**

**File No. 120557-001**

**Blue Care Network of Michigan**  
**Respondent**

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**Issued and entered**  
**this 20<sup>th</sup> day of September 2011**  
**by R. Kevin Clinton**  
**Commissioner**

**ORDER**

**I. BACKGROUND**

On April 12, 2011, XXXXX, on behalf of her minor son XXXXX (Petitioner), filed a request for an external review with the Commissioner of Financial and Insurance Regulation under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.*

The Commissioner notified Blue Care Network of Michigan (BCN) of the request and asked for the information it used to make its final adverse determination. On April 19, 2011, the Commissioner received BCN's response and, after a preliminary review of the material submitted, accepted the request for external review.

The issue in this external review can be decided by an analysis of the contract that defines the Petitioner's health care benefits. The Commissioner reviews contractual issues under MCL 500.1911(7). This matter does not require a medical opinion from an independent review organization.

**II. FACTUAL BACKGROUND**

The Petitioner, born February 13, XXXXX, is a member of BCN, a health maintenance organization, as an eligible dependent. His health care benefits are outlined in the BCN 1 Certificate of Coverage (the certificate).

The Petitioner seeks reimbursement for a human papillomavirus (HPV) vaccination administered on February 14, 2011, and coverage for two remaining vaccinations in the HPV series.

BCN denied coverage for the HPV vaccinations, stating they were not a benefit for males. The Petitioner appealed the denial. At the conclusion of its internal grievance process, BCN maintained its denial and issued a final adverse determination dated April 7, 2011. The Petitioner now seeks an external review from the Commissioner.

## **II. ISSUE**

Did BCN properly deny coverage for the HPV vaccinations for the Petitioner?

## **III. ANALYSIS**

### Petitioner's Argument

In a letter dated April 12, 2011, included with the request for external review, the Petitioner's mother indicated:

I am appalled that with Blue Care Network's talk of preventative care, that they would not follow the CDC's guidelines and physician recommendations for coverage of the vaccination of both girls and boys to prevent the spread of HPV and genital warts. . . . It is wrong to discriminate against boys' receiving this vaccination series, as they are at as much risk as the girls.

The Petitioner's mother believes BCN should follow the guidelines of the Centers for Disease Control and Prevention (CDC) and cover HPV vaccinations for both males and females as a preventive health care service. She also wishes her provider had informed her that BCN would not cover the vaccination before it was administered.

The Petitioner's mother wants BCN to reimburse her for her out-of-pocket cost for the initial HPV vaccination and cover the subsequent vaccinations in the series.

### Respondent's Argument

In its April 7, 2011, final adverse determination, BCN responds:

The [grievance] Panel determined that BCN only covers the HPV vaccine for eligible females from 9-26 years of age and as such your grievance remains denied.

Earlier, in a letter of March 24, 2011, BCN advised the Petitioner's mother:

...[T]he HPV vaccine is not a covered benefit for males with Blue Care Network (BCN). Even though it has recently been approved by the Food and Drug

Administration (FDA), BCN is not covering this vaccine for males. At this time it is only a covered benefit for eligible female members between the ages of 9 to 26 years. Therefore, your request is denied.

Commissioner's Review

The Insurance Code requires BCN, as a health maintenance organization (HMO), to provide "basic health services." MCL 500.3519(3). "Basic health services" includes "preventive health services." MCL 500.3501(b)(ix). Immunizations are a type of preventive health service. However, there is nothing in the Insurance Code or elsewhere in state law that specifies what type of immunizations must be provided by an HMO as a part of preventive health services. Therefore, the Commissioner looks to the reasonableness of the HMO's determination as to what immunizations are covered.

The certificate (p. 4) has the following provision regarding BCN's coverage for immunizations:

***1.08 Preventive and Early Detection Services***

\* \* \*

Preventive Services include but are not limited to the following:

\* \* \*

- Immunizations (pediatric and adult) as recommended by the Advisory Committee on Immunization Practices or other organizations recognized by BCN. [Underlining added]

BCN has chosen to cover those routine immunizations that are recommended by the Advisory Committee on Immunization Practices (ACIP). The Commissioner concludes that the ACIP recommendations are a reasonable standard for BCN to use. The ACIP consists of experts in the immunization field who provide advice and guidance to the federal government, including the Centers for Disease Control and Prevention (CDC). The ACIP develops written recommendations for the routine administration of vaccines to children and adults in the civilian population that include age for vaccine administration, number of doses and dosing intervals, and precautions and contraindications.

BCN's medical policy entitled "Human Papillomavirus (HPV) Vaccination for Males" (effective 11/1/10), explains BCN's position:

There are now two HPV vaccines available for use in the United States - Gardasil and Cervarix. In 2006, Gardasil received approval from the U.S. Food and Drug Administration (FDA) for use in females ages 9 to 26 for HPV types 6, 11, 16 and 18. Gardasil is a quadrivalent (having four valences) vaccine (HPV4) designed to work against two oncogenic types of the virus (HPV 16 and 18) and two non-oncogenic virus types (HPV 6 and 11). Cervarix was approved by the FDA in 2009 for use in females ages 10 through 25 years. Cervarix is a bivalent

(having two valences) vaccine (HPV2) directed against two oncogenic virus types (HPV 16 and 18).

\* \* \*

In May 2010, the Advisory Committee on Immunization Practices (ACIP) provided guidance to allow Gardasil for use in males on a permissive basis rather than as a routine vaccination. The ACIP's position statement indicates that the quadrivalent HPV vaccine "may be given to males aged 9 through 26 years to reduce their likelihood of acquiring genital warts." . . .

\* \* \*

### **Medical Policy Statement**

The safety and effectiveness of the quadrivalent Human Papillomavirus (HPV) vaccine, Gardasil, for use in males have been established. It is approved by the U.S. Food and Drug Administration (FDA) for use in males. However, the HPV vaccine has not been clearly recommended by the American Committee on Immunization Practices (ACIP) as a routine vaccination in males. . . .

BCN's medical policy reflects the position of the ACIP that routine HPV vaccinations for males are not recommended. The CDC's "Morbidity and Mortality Weekly Report" for May 28, 2010,<sup>1</sup> stated:

On October 16, 2009, the Food and Drug Administration licensed quadrivalent human papillomavirus vaccine . . . for use in males aged 9 through 26 years for prevention of genital warts caused by human papillomavirus (HPV) types 6 and 11. HPV4 had been licensed previously for use in females aged 9 through 26 years for prevention of HPV 6, 11, 16, and 18-related outcomes (i.e., vaginal, vulvar, and cervical precancers and cancers and genital warts). The Advisory Committee on Immunization Practices (ACIP) recommends routine vaccination of females at age 11 or 12 years and catch-up vaccination for females aged 13 through 26 years. [footnote omitted] On October 21, 2009, ACIP provided guidance that HPV4 may be given to males aged 9 through 26 years to reduce their likelihood of acquiring genital warts; ACIP does not recommend HPV4 for routine use among males. . . .

Since routine HPV vaccinations for males are not recommended by the ACIP, the Commissioner concludes that BCN correctly denied the Petitioner's request based on its preventive services benefit as stated in the certificate.

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<sup>1</sup> [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5920a5.htm?s\\_cid=mm5920a5\\_e](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5920a5.htm?s_cid=mm5920a5_e) (accessed September 14, 2011).

#### **IV. ORDER**

The Commissioner upholds BCN's April 7, 2011, final adverse determination. BCN is not required to cover the HPV vaccine for the Petitioner.

This is a final decision of an administrative agency. Under MCL 550.1915, any person aggrieved by this Order may seek judicial review no later than 60 days from the date of this Order in the circuit court for the county where the covered person resides or in the circuit court of Ingham County. A copy of the petition for judicial review should be sent to the Commissioner of Financial and Insurance Regulation, Health Plans Division, Post Office Box 30220, Lansing, MI 48909-7720.